

### **REMARKS**

Regarding pending claims 1-20, the Examiner requires multiple species elections to:

- (i) “a particular type of cancer to be inhibited” (or alternatively, the tissue type to be targeted for treatment) in the method of claim 1; and
- (ii) “a particular fatty acid synthase inhibitor formula,” as presently recited in dependent claims 18, 19 and 20.

**Applicants elect:**

- (i) the targeted tissue type as lung tissue (claim 8 and claim 12); and
- (ii) the fatty acid synthase inhibitor, C75 (claim 20).

**Both species elections are made with traverse.**

Claims 1-8, 12 and 16-20 read on species (i): lung tissue.

Claims 1-17 and 20 read on species (ii): the fatty acid synthase inhibitor, C75.

The Examiner takes the position that claims 1-20 of the above-identified invention recite the “special technical feature” (as required under PCT Rule 13.1 for a U.S. national phase application) as “the fatty acid synthase inhibitor in the treatment of cancer,” but that this designation does not rise to the level of “a special technical feature” under PCT Rule 13.2 because it is shown in the prior art.<sup>1</sup> The Examiner attempts to bolster this position by relying on Kuhajda *et al.* (U.S. Patent No. 5,759,837; “the ‘837 patent”) as disclosing “fatty acid synthase inhibitors in the treatment of cancer” and thus, “no special technical feature exist[s] because the invention fails to make a contribution over the prior art with respect to novelty and inventive step.”<sup>2</sup> Applicants respectfully disagree. Applicants are more than familiar with the ‘837 patent, as Dr. Kuhajda is a named inventor on both the ‘837 patent and the above-identified application. The ‘837 patent discloses a method of ameliorating tumor burden, i.e., treating pre-existing cancer cell growth, in mammals having a carcinoma tumor which contains cells that are

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<sup>1</sup> See Office Action at pg. 3, para. 2.

dependent on endogenously synthesized fatty acid.<sup>3</sup> The '837 patent further discloses that cancerous tumor cells usually over-express a protein with FAS activity, and that tumor burden may be reduced by administration of a FAS inhibitor. The '837 patent is entirely lacking, however, in any teaching or disclosure pertaining to methodology of inhibiting cancer development by the administration of a FAS inhibitor; neither does the '837 patent contain any speculative language suggesting the same. Indeed, the '837 patent is directed solely to a method of treating pre-existing cancer cell growth, and that "preventing synthesis of fatty acids by the cell may be used to treat carcinoma."<sup>4</sup> To this end, the '837 patent discloses the effect of FAS inhibitors on pre-existing carcinoma cells.<sup>5</sup> Specifically, FAS inhibitors are disclosed to be anti-proliferative to breast carcinoma cells over-expressing OA-519, a protein that has been found to have fatty acid synthase activity which is a required enzyme activity for the growth of carcinomas.<sup>6</sup> The '837 patent further discloses that the administration of FAS inhibitors *in vitro* to ZR-75-1 cancer cells results in over 80% growth amelioration.<sup>7</sup>

However, the '837 patent neither discloses or suggests administering FAS inhibitors for inhibiting cancer development in pre-cancerous cells, as required by the claims of the instant invention. Thus, while it was known that FAS inhibitors can ameliorate pre-existing cancer cell growth, it was not known that treatment with FAS inhibitors would inhibit cancer development. To this end, the instant invention provides "a method for treating the pre-cancerous state in a subject (i.e., inhibiting cancer development)."<sup>8</sup> The Specification as filed defines the term "inhibiting" as "delaying cancer development . . . by stimulating, inducing or triggering apoptosis . . . in pre-cancerous cells."<sup>9</sup> The Specification further defines "cancer development" as "the initial appearance of cancerous cells," i.e., "cells which have the property of autonomous proliferation and have invaded adjacent tissues."<sup>10</sup> In this regard, a method inhibiting cancerous development in pre-cancerous cells is significantly distinguished from a method of treating the

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<sup>2</sup> *Id.* at pg. 3, para. 3.

<sup>3</sup> *See* the '837 patent at col. 7, lns. 16-19

<sup>4</sup> *Id.* at col. 9, lns. 16-17.

<sup>5</sup> *Id.* at col. 26, lns. 28-36.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at col. 26, lns. 36-61.

<sup>8</sup> *See* Specification at pg. 6, lns. 10-12.

<sup>9</sup> *Id.* at pg. 8, lns. 6-9.

<sup>10</sup> *Id.* at pg. 8, lns. 10-13.

growth of pre-existing cancerous tumor cells. Thus, Applicants respectfully take the position that the '837 patent does not disclose nor suggest a method for inhibiting the development of cancer in pre-cancerous cells. And to this end, Applicants respectfully take the position that claims 1-20 of the instant invention meet the requirement of reciting a "special technical feature" as required by PCT Rule 13.1 and as further defined under PCT Rule 13.2.

Applicants respectfully submit that upon allowance of a generic claim, they may request rejoinder of claims directed to non-elected species written in dependent form or which in the alternative contain all limitations of the allowed generic claim, as in accordance with the provisions of M.P.E.P. § 821.04 and as indicated on page 5 of the outstanding Office Action. Additionally, Applicants also reserve the right to file one or more additional continuing applications directed to non-elected subject matter.

Should the Examiner have any questions or comments with respect to this Response, it is respectfully requested that the Examiner telephone Applicants' attorney at (215) 299-3830 to discuss any additional matters.

Respectfully submitted,

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